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THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Yeh et al.

GROUP: 1615

SERIAL NO: 09/847,017

EXAMINER: Unknown

FILED: May 1, 2001

FOR: A PROCESS FOR THE PREPARATION OF DIRECT  
TABLETTING FORMULATIONS AND AIDS

Assistant Commissioner of Patents  
Washington, D.C. 20231

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Sir:

INFORMATION DISCLOSURE STATEMENT

In compliance with 37 C.F.R. §§1.56, 1.97, and 1.98, Applicant submits copies of the documents listed on the attached Form PTO-1449. Also enclosed is a statement as to the relevancy of the non-translated foreign patents.

The Commissioner is authorized to charge Deposit Order Account No. 19-0079 for any further fee that is required.

Respectfully submitted,

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I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United State Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Commissioner of Patents and Trademarks, Washington, D.C. 20231.

*Handwritten signature of Sarah Kennedy*  
Sarah Kennedy  
7/31/01  
Date

**Comments on non-English-language references pursuant to Rule 98 for the  
Information Disclosure Statement of Patent Application Serial No. 09/847,017 (A  
Process for the Preparation of Direct Tableting Formulations and Aids)**

**DE-C 3 506 276** disclosed a combination of  $\alpha$ -lactose monohydrate and powdered cellulose for direct tableting. Although this composition has a high binding capacity, it has no disintegration-promoting properties, especially when the compressive forces are relatively high.

**DE-A 35 05 433** disclosed another combination of  $\alpha$ -lactose monohydrate and polyvinyl pyrrolidone as binder, and crosslinked, insoluble polyvinyl pyrrolidone to promote disintegration. This direct tableting aid has excellent flow properties and results, without further addition of a disintegrant, in rapidly disintegrating tablets. However, it is less suitable for high-dose active substances whose compressibility is poor, because its uptake capacity for active substances to form tablets with sufficient mechanical stability is limited.